BRIEFING FOR ANNA WILDEMAN
CALIFORNIA SELENIUM NOTICE OF PROPOSED RULE MAKING
June 21, 2018

Purpose: Provide overview of EPA's upcoming proposed rule to establish an aquatic life and aquatic-dependent wildlife criterion for selenium in California which will replace CA's current federally promulgated selenium criterion. Our deadline to propose this rule is November 30, 2018.

Background

Lawsuit

- In 2013, EPA was sued by the Our Children's Earth Foundation and Ecological Rights Foundation, two California-based non-profits ("plaintiffs").
- Among plaintiffs' allegations were that EPA violated the CWA, ESA, and APA by failing to promulgate mercury (Hg) and selenium (Se) criteria to protect threatened and endangered aquatic life and aquatic-dependent wildlife, as agreed to during ESA consultation over the 2000 California Toxics Rule (CTR) (See Relevant Consent Decree language in Appendix C).
- EPA and plaintiffs settled via consent decree in August 2014, requiring:
    - EPA to propose statewide Hg criteria (except where already in place) by June 2017, and finalize by six months after ESA consultation, or approve CA-adopted criteria. **EPA fulfilled this obligation by approving the state's package on 7/14/17.**
    - EPA to propose Se criteria for the rest-of-California (outside Bay and Delta) by November 2018 or approve CA-adopted criteria. **California has confirmed it does not intend to pursue state rulemaking to adopt Se criteria statewide.**
        - Per the terms of the consent decree, EPA to request initiation of consultation with the Services no later than 9 months after proposal, and to finalize rule within 6 months of receiving final response from the Services.
        - Note: Since EPA proposed Bay and Delta Se criteria by June 2016, EPA's deadline for proposing Se criteria for the rest-of-California was automatically extended from November 2016 to November 2018. **EPA's current CD deadline to propose Se criteria statewide is November 30, 2018.**

Regulatory Process and Workgroup

- The rule is designated Tier 3, and OMB determined that the proposed rule is significant under EO 12866.
- The workgroup includes members from SHPD, Region 9, HECD, OP, ORD, OGC, and Region 9 ORC.
- A draft rule has been developed and is currently under management review.
- The econ analysis is currently under management review
    - **Ex. 5 Deliberative Process (DP)**
    - Annual costs include capital costs annualized over 20 years at 3% plus annual operating and maintenance costs. Annual costs also reflect a 5-year implementation period for point sources and a 13-year implementation period for nonpoint source BMPs. Total TMDL development costs are uniformly distributed over 13 years.
- Outstanding issues to address with OMB regarding the Regulatory Flexibility Analysis and Executive Order on Federalism.

Scientific Basis for the Rule

- EPA published an updated 304(a) aquatic life chronic criterion (See Appendix A) for freshwater for selenium in 2016. This criterion was the result of over 20 years of work that included an international expert workshop, model derivation with ORD and USGS, EPA workgroup reviews, external peer review, and 2 separate public comment periods.
- The science on selenium, as reflected in the 2016 304(a) criterion, indicates that selenium toxicity to aquatic life is primarily based on organisms consuming selenium-contaminated food rather than by being exposed only to selenium dissolved in water. The criterion is expressed both in terms of fish tissue concentration (egg/ovary, whole body, muscle) and water concentration (lentic, lotic).
- Although selenium may cause acute toxicity at high concentrations, the most deleterious effect on aquatic organisms is due to its bioaccumulative properties; these chronic effects are found at lower concentrations than acute effects. The science indicates that selenium toxicity occurs primarily through transfer to the eggs and subsequent reproductive effects. **Consequently, in harmony with the recommendations of expert panels and with peer review and public comments on previous U.S. EPA drafts, the Agency developed a chronic criterion reflective of the reproductive effects of selenium concentrations on fish species and did not include an acute criterion.**
- EPA's 2016 304(a) aquatic life criterion is the basis for EPA's proposal for California.
- HECD, SHPD, and R9 have completed an extensive technical support document (TSD) deriving a selenium criterion that is protective of aquatic life and aquatic-dependent wildlife.
- The TSD was peer-reviewed in late 2017. Reviewers generally supported the approach, recommending only a few minor changes or enhancements (See Appendix B).
- Four out of five reviewers believed that the criterion would be protective of aquatic-dependent wildlife (See Appendix B).
- Revisions to address peer review comments are nearly complete (See Appendix B for peer review summary).

Criterion

Overview

- As currently written, the draft rule proposes EPA's 2016 304(a) selenium aquatic life criterion for freshwater (fish tissue and water concentration elements) with the new addition of a bird egg element, as one comprehensive criterion structure to protect both aquatic life and wildlife designated uses. Additionally, the proposed rule takes comment on an alternative structure, whereby the rule would consist of two separate criteria for the two separate uses.

Aquatic-Dependent Wildlife

- EPA conducted an extensive review of literature quantifying the toxicity of selenium to aquatic-dependent wildlife and derived a bird egg selenium threshold.
- A bird egg selenium threshold of 11.2 mg/kg dw was derived from three selenium toxicity studies on mallards.
- Mallards were determined to be the most sensitive bird species for which selenium toxicity studies have been conducted.
- EPA utilized the same model as used to derive the 2016 304(a) criterion for aquatic life, and applied it to birds known to be present in CA with their corresponding diets.

- In this analysis, EPA found that the selenium water column-based criterion elements previously derived by EPA (2016) would also be protective of aquatic-dependent wildlife. Therefore, EPA is proposing to include the 2016 304(a) water column-based criterion elements as the applicable water column elements for California to protect aquatic-dependent wildlife.

Freshwater Criterion Applicability

- The consent decree specifies that selenium criteria need to be promulgated for freshwaters (< 1 ppt salinity) in California (See Appendix C for CD Language).
- The CTR, however, is applicable in California for inland surface waters, enclosed bays, and estuaries which have a range of salinities well above 1 ppt.
- Additionally, CTR language lays out that where a water is between 1 and 10 ppt salinity, the more stringent criterion (fw vs. sw) will apply to that water (See Appendix D for CTR language). CA has both fw and sw Se criteria in place for inland surface waters, enclosed bays, and estuaries. Their current fw criterion will be replaced by the fw criterion in this proposed rule.
- Enclosed bays and estuaries (outside SF Bay/Delta) are technically not included in EPA's promulgation, but areas of salinity between 1 and 10 may be impacted by the existing applicability rules in the CTR. We are describing this in the preamble.
- The econ analysis will account for these water bodies as well as the truly fresh waters.

Statutory Authority to Propose and Proposed Rule Applicability

- Currently, California has EPA's 1987 304(a) freshwater (5 µg/L chronic) selenium criterion (promulgated by EPA in the 2000 CTR) in place statewide and several EPA-approved site-specific criteria. There is no statewide acute criterion for freshwater.
    - Through promulgation of the CTR, California also has EPA's 1987 304(a) saltwater criteria (290 µg/L acute and 71 µg/L chronic) in place.
- While EPA proposed a statewide acute criterion as part of the 1997 CTR proposal, EPA "reserved" (did not promulgate) an acute criterion in the final CTR. This was due to the Biological Opinion the Services issued in 2000 in which EPA agreed to reserve the acute, because the Services did not believe it was protective, and to develop and promulgate protective acute and chronic selenium criteria for the state (See Appendix D & E).
- Although the Biological Opinion concluded that 5 µg/L chronic was not protective for T&E species, EPA promulgated it in the 2000 CTR because the Services concluded that there would be no jeopardy if EPA proposed revised acute and chronic criteria by January 2003.
- CWA section 303(c)(4) authorizes EPA to promulgate state standards only when (A) EPA disapproves a state submission or (B) the Administrator determines a new standard is necessary to meet the Act's requirements. Because CA has not submitted a selenium standard, EPA must include an Administrator Determination as part of its proposal.
- California has several site-specific chronic criteria for selenium. EPA is proposing its revised criterion for all the waters where these site-specific criteria apply except one.

Collaboration with California

- EPA (HQ/R9) had a kick-off call with California on 2/9/18 and they expressed that they have no intention to go through a state rulemaking for selenium.
- EPA had another call on 5/22/18 and 6/6/18 to discuss the content of the rule with CA. Most notably, they expressed a desire to have the bird egg value as part of the criterion structure.
- We are continuing to engage with the State and are planning for another call.

Planned Timeline for Next Steps

Key Milestone	Start Date	End Date
OW AA Review of Proposed Rule	6/21/18	7/5/18
OP Review	7/6/18	7/20/18
OMB 90-day Review	7/23/18	10/22/18
Finalize Rule and Econ Analysis	10/23/18	10/30/18
OW AA Review	10/31/18	11/14/18
OP/OEX Review	11/15/18	11/29/18
Administrator Signature		11/30/18

Appendix A: Proposed California Freshwater Selenium Ambient Chronic Water Quality Criterion for Protection of Aquatic Life and Aquatic-Dependent Wildlife.

Media Type	Bird Tissue	Fish Tissue[1]		Water Column[4]	
Criterion Element	**Bird Egg[2]**	**Egg-Ovary[2]**	**Fish Whole Body or Muscle[3]**	**Monthly Average Exposure**	**Intermittent Exposure[5]**
Magnitude	11.2 mg/kg dw	15.1 mg/kg dw	8.5 mg/kg dw whole body or 11.3 mg/kg dw muscle (skinless, boneless filet)	1.5 µg/L in lentic aquatic systems 3.1 µg/L in lotic aquatic systems	$WQC_{int} = \frac{WQC_{30-day} - C_{bkgrnd}(1 - f_{int})}{f_{int}}$
Duration	Instantaneous measurement[6]	Instantaneous measurement[6]	Instantaneous measurement[6]	30 days	Number of days/month with an elevated concentration
Frequency	Not to be exceeded	Not to be exceeded	Not to be exceeded	Not more than once in three years on average	Not more than once in three years on average

1. Fish tissue elements are expressed as steady-state.
2. Fish Egg-Ovary supersedes any whole-body, muscle, or water column element for that taxon when fish egg-ovary are measured. Bird Egg supersedes water column elements for that taxon when both are measured.
3. Fish whole-body or muscle tissue supersedes the water column element when both fish tissue and water concentrations are measured.
4. Water column values are based on dissolved total selenium in water and are derived from fish tissue values via bioaccumulation modeling. Water column values are the applicable criterion element in the absence of bird egg data and steady-state condition fish tissue data.
5. Where $WQC_{30\text{-}day}$ is the water column monthly element, for either lentic or lotic waters; C_{bkgrnd} is the average background selenium concentration, and f_{int} is the fraction of any 30-day period during which elevated selenium concentrations occur, with f_{int} assigned a value ≥0.033 (corresponding to 1 day).
6. Fish tissue and bird tissue data provide instantaneous point measurements that reflect integrative accumulation of selenium over time and space in bird or fish population(s) at a given site.

Appendix B: Summary of Peer Review Comments and Proposed Responses

The peer review panel consisted of five senior scientists with expertise/experience in toxicity of selenium in aquatic life and/or aquatic-dependent wildlife, aquatic ecotoxicology, statistical analyses and data interpretation, and environmental occurrence and fate of selenium in the environment.

- The peer reviewers stated that the technical approach for deriving the criterion was logical and scientifically defensible.

- Most of the peer reviewers (4 out of 5) stated that the criterion would likely be protective of aquatic life and aquatic-dependent wildlife inhabiting California, including T&E species.
    - Two reviewers expressed concerns with the protectiveness of the bird egg criterion for all aquatic-dependent wildlife given the relatively limited selenium toxicity data available.
        - One reviewer recommended the development of tables with details of selenium toxicity studies to demonstrate the relative sensitivity of birds to selenium
            a) Proposed Response: Suggested tables have been added as an appendix of TSD draft.
        - Another reviewer stated that an EC_{10} value of 7.3 µg/g dw (Beckon et al. 2008) would be most scientifically defensible and recommended that a biphasic model be used to derive an EC_{10} and/or that an uncertainty factor be applied to the bird criterion derived from mallard toxicity data to account for potential differences in sensitivity between species.
            a) Proposed Response: An explanation of EPA's current and previous (as stated previously in GSL approval) conclusions of the biphasic model and why it was not used to derive an EC_{10} for selenium, including a summary EPA's interpretation of the approach used in Beckon et al. 2008. And the reason for not applying an uncertainty factor to the bird criterion given the current toxicity literature for selenium and the use of the most sensitive species to derive the aquatic-dependent wildlife criterion.
    - Three of the five reviewers stated that the food web modeling was well characterized and that the trophic transfer factors (TTFs) appeared to be appropriate.
        - One reviewer stated that the approach used to determine if a relationship between paired egg and diet selenium data was adequate for producing a TTF was debatable and recommended that we consider other tools (such as an outlier analysis) for deciding if a relationship between paired data was adequate.
            a) Proposed Response: An outlier analysis was conducted on these paired data and TTFs were recalculated based on this outlier analysis.
        - One reviewer stated that the use of TTFs based on mean or median values would result in too low a level of protection.
            a) Proposed Response: An explanation of EPA's use of mean and median values in the food web modeling, which are presented in the draft TSD and were discussed in the final 2016 304(a) selenium criterion.

Appendix C: Relevant Consent Decree Language

3. "Selenium Criteria" mean one or more water quality criteria to protect aquatic life and aquatic-dependent wildlife from the harmful long-term effects of selenium, including protection from harmful long-term effects of short-term exposures to selenium. Such water quality criteria will consist of numeric values that EPA determines are protective of the designated uses of the applicable waters, pertaining to aquatic life and aquatic-dependent wildlife.

6. "Bay Delta" means the waters covered by the 1992 NTR promulgation of selenium aquatic life criteria for two water bodies in the San Francisco Bay Delta system and a third intervening water body. These three criteria promulgations together covered selenium for an extended segment reaching from San Francisco Bay upstream through the Delta and into the lower reaches of the San Joaquin River system. The three segments are, going upstream: (1) "Waters of San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta"; (2) "Waters of the San Joaquin River from the mouth of the Merced River to Vernalis"; and (3) "Waters of Salt Slough, Mud Slough (north) and the San Joaquin River, Sack Dam to the mouth of the Merced River." 57 Fed. Reg. 60848, 60921, codified at 40 C.F.R. § 131.36(b)(1)(ii).

9. In Section III.A. (respecting Selenium Criteria), "Rest of California" means waters of the United States in California that are ***fresh waters*** *and are not part of the "Bay Delta."*

12. "Fresh Waters" are those with 1 ppt or less of salinity 95% or more of the time. 40 C.F.R. § 131.36(c)(3)(i).

A. Selenium Criteria:

14. Except as provided in Paragraphs 15 or 18, EPA shall propose Selenium Criteria for the Rest of California by November 30, 2016.

15. In the event that EPA proposes Selenium Criteria for Salt and Estuarine Waters of the Bay Delta by June 30, 2016, EPA will propose Selenium Criteria for the Rest of California by November 30, 2018.

16. EPA shall request initiation of any necessary ESA Section 7(a)(2) consultation with the Services on the proposed Selenium Criteria for the Rest of California no later than nine (9) months after the date EPA proposes the criteria.

17. Except as provided in paragraph 18, EPA shall finalize its proposal of Selenium Criteria for the Rest of California within six (6) months of the later of the following dates: (1) the date of EPA's conclusion (if any) that it will not seek ESA Section 7(a)(2) consultation because some or all of the proposed Selenium Criteria have "no effect" on any listed ESA species or designated critical habitat; (2) the date of the Services' written concurrence(s) with any EPA conclusion that some or all of the proposed Selenium Criteria are "not likely to adversely affect" listed ESA species or designated critical habitat pursuant to 50 C.F.R. §§ 402.13(a) and 402.14(b); or (3) the date of the Services' Biological Opinion(s) concluding any formal consultation on the proposed Selenium Criteria pursuant to 50 C.F.R. § 402.14(l).

18. In the event that EPA approves, pursuant to Section 303(c)(3) of the CWA, Selenium Criteria submitted by the State of California for all or any portion of the Rest of California, EPA's obligation to propose or finalize a proposal for Selenium Criteria under this Section for that specific area is null and void.

Internal, deliberative, pre-decisional. Do not quote, cite or release.

19. This Consent Decree shall not be construed for any purpose as a requirement that EPA propose or finalize any proposal for selenium criteria for the Bay Delta.

Appendix D: Relevant CTR Language

ESA Language

F. Derivation of Criteria, a. Freshwater Acute Selenium Criterion, last paragraph: *The preamble to the August 5, 1997, proposed rule provided a lengthy discussion of this proposed criterion for the State of California. See 62 FR 42160–42208. EPA incorporates that discussion here as part of this rulemaking record. In 1996, a similar discussion was included in the proposed rule for the Great Lakes System. Commenters questioned several aspects of the Great Lakes proposal. EPA is continuing to respond to those comments, and to follow up with additional literature review and toxicity testing. In addition, the U.S. FWS and U.S. NMFS (collectively, the Services) are concerned that EPA's proposed criterion may not be sufficiently protective of certain threatened and endangered species in California. Because the Services believe there is a lack of data to show for certain that the proposed criterion would not affect threatened and endangered species, the Services prefer that EPA further investigate the protectiveness of the criterion before finalizing the proposed criterion. Therefore, EPA is not promulgating a final acute freshwater selenium criterion at this time.*

M. Endangered Species Act, last paragraph: *In order to ensure the continued protection of Federally listed threatened and endangered species and to protect their critical habitat, EPA agreed to reserve the aquatic life criteria for mercury and the acute freshwater aquatic life criterion for selenium. The Services believe that EPA's proposed criteria are not sufficiently protective of Federally listed species and should not be promulgated. EPA agreed that it would reevaluate these criteria in light of the Services concerns before promulgating them for the State of California. Other commitments made by EPA are described in a letter to the Services dated December 16, 1999; this letter is contained in the administrative record for today's rule.*

Salinity Language

Preamble: *Because a distinct separation generally does not exist between freshwater and saltwater aquatic communities, EPA is establishing the following: (1) The freshwater criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) saltwater criteria apply at salinities of 10 parts per thousand and above at locations where this occurs 95% more of the time; and (3) at salinities between 1 and 10 parts per thousand the more stringent of the two apply unless EPA approves the application of the freshwater or saltwater criteria based on an appropriate biological assessment. The percentiles included here were selected to minimize the chance of overlap, that is, one site meeting both criteria. Determination of these percentiles can be done by any reasonable means such as interpolation between points with measured data or by the application of calibrated and verified mathematical models (or hydraulic models). It is not EPA's intent to require actual data collection at particular locations. In the brackish water transition zones of estuaries with varying salinities, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply. In evaluating appropriate data supporting the alternative set of criteria, EPA will focus on the species composition as its preferred method. This assignment of criteria for fresh, brackish and salt waters was developed in*

consultation with EPA's research laboratories at Duluth, Minnesota and Narragansett, Rhode Island. The Agency believes such an approach is consistent with field experience. Paragraph (d) in 40 CFR 131.38 lists the designated water and use classifications for which the criteria apply. The criteria are applied to the beneficial use designations adopted by the State of California; EPA has not promulgated any new use classifications in this rule.

Appendix E: Relevant Language from Final Biological Opinion for CTR

Modifications to the Final CTR

Based on the Services' April 9,1999, revised draft biological opinion EPA submitted the following proposed modifications to the CTR in their December 16, 1999, letter to the Services. These modifications will be incorporated by reference into section M of the preamble of EPA's final promulgation of the CTR. They are recorded here to reflect EPA's agreed-upon modifications to the proposed CTR.

I. EPA Modifications Addressing the Services' April 9, 1999 draft Reasonable and Prudent Alternatives for Selenium:

A. EPA will reserve (not promulgate) the proposed acute aquatic life criterion for selenium in the final CTR.

B. EPA will revise its recommended 304(a) acute and chronic aquatic life criteria for selenium by January 2002. EPA will propose revised acute and chronic aquatic life criteria for selenium in California by January of 2003. EPA will work in close cooperation with the Services to evaluate the degree of protection afforded to listed species by the revisions to these criteria. EPA will solicit public comment on the proposed criteria as part of its rulemaking process, and will take into account all available information, including the information contained in the Services' Opinion, to ensure that the revised criteria will adequately protect federally listed species. If the revised criteria are less stringent than those proposed by the Services in the Opinion, EPA will provide the Services with a biological evaluation/assessment on the revised criteria by the time of the proposal to allow the Services to complete a biological opinion on the proposed selenium criteria before promulgating final criteria. EPA will provide the Services with updates regarding the status of EPA's revision of the criterion and any draft biological evaluation/assessment associated with the revision. EPA will promulgate final criteria as soon as possible, but no later than 18 months, after proposal. EPA will continue to consult, under section 7 of ESA, with the Services on revisions to water quality standards contained in Basin Plans, submitted to EPA under CWA section 303, and affecting waters of California containing federally listed species and/or their habitats. EPA will annually submit to the Services a list of NPDES permits due for review to allow the Services to identify any potential for adverse effects on listed species and/or their habitats. EPA will coordinate with the Services on any permits that the Services identify as having potential for adverse effects on listed species and/or their habitat in accordance with procedures agreed to by the Agencies in the draft MOA published in the Federal Register at 64 FR 2755 (January 15, 1999) or any modifications to those procedures agreed to in a finalized MOA.

Terms and Conditions

In order to comply with the Act, EPA must comply with the following terms and conditions, which implement the reasonable and prudent measures described above and outline required reporting/monitoring requirements. These terms and conditions are non-discretionary.

1. The following terms and conditions implement reasonable and prudent measure number one for the proposed numeric criteria for selenium.

a) EPA will reserve (not promulgate) the proposed acute aquatic life criterion for selenium in the final CTR.

b) EPA will revise its recommended 304(a) acute and chronic aquatic life criteria for selenium by January 2002. In revising these criteria EPA will work in close cooperation with the Services, inviting scientists from each Service to participate on peer review panels and as observers on criteria revision teams.

c) EPA will propose revised acute and chronic aquatic life criteria for selenium in California by January 2003.

d) If EPA's proposed acute or chronic criterion for selenium in California are less stringent than the ***criteria suggested in this opinion (< 2 ug/L),*** *EPA will provide the Services with a biological evaluation/assessment and request for formal consultation on the revised criterion (or criteria) by January 2003. EPA's biological evaluation/assessment on the revised criterion (or criteria) will specifically address semi-aquatic wildlife species.*

e) EPA will promulgate final acute and chronic criteria for selenium in California no later than June 2004.

f) EPA will provide the Services in California with semi-annual reports regarding the status of EPA's revision of the selenium criteria and accompanying draft biological evaluation/assessment associated with the revision. The first report will be provided by June 30, 2000.

g) EPA will identify water bodies in the State of California where selenium criteria necessary to protect federally listed species are not met (selenium-impaired water bodies), and will annually submit to the Services a list of NPDES permits due for review to allow the Services and EPA to identify any potential for adverse effects on listed species and/or their habitats. A list of selenium-impaired water bodies and the first NPDES permit review shall occur prior to October 2000. EPA will annually submit to the Services a list of NPDES permits due for review to allow the Services and EPA to identify any potential for adverse effects on listed species and/or their habitats. The first NPDES permit review shall occur prior to October 2000.

h) EPA will coordinate with the Services on any permits containing limits for selenium that the Services (or EPA) identify as having potential for adverse effects on listed species and/or their habitat in accordance with procedures agreed to by the Agencies in the draft MOA published in the Federal Register at 64 FR 2755 (January 15, 1999). If discharges are identified that have the potential to adversely affect federally listed species and/or critical habitat, EPA will work with the Services and the State of California to address the potential effects to the species. This will include, where appropriate, decreasing the allowable discharge of selenium consistent with this opinion. Among other options to resolve the issue, the EPA may make a formal objection to a permit and federalize the permit where consistent with EPA's CWA authority. If EPA objects to a NPDES permit, EPA will follow the permit objection procedures outlined in 40 CFR 123.44 and coordinate with the Services. If EPA assumes permit issuing authority for a NPDES permit, EPA will consult with the Services prior to issuance of the permit (as a federal action) as appropriate under section 7 of the ESA. Under such circumstances EPA would prepare and submit a biological evaluation/assessment on those permits for purposes of completing consultation.